

# Bionano Corporate Overview

September 2024

**bionano**<sup>™</sup>



**Safe harbor statement** - This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “may,” “will,” “expect,” “plan,” “anticipate,” “estimate,” “intend,” “should,” “believe,” “would,” “could,” “potential,” “outlook,” “guidance,” “goal” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances and the negatives thereof) convey uncertainty of future events or outcomes and are intended to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: (i) our expectations regarding product uptake, revenue growth, market development and adoption of OGM, including growth in publications highlighting the utility and applications of OGM; (ii) our growth prospects and future financial and operating results; (iii) growth of our OGM system installed base and sales of our flowcells; (iv) increase in the adoption and utilization of OGM; (v) the impact of our investment in R&D and commercial and educational initiatives, including timely and successful launch of our planned product developments and clinical study results; (vi) our ability to stay in front of competitors’ improvements; (vii) our estimates of anticipated market opportunity and underlying assumptions; (viii) our quarterly and annual revenue outlook; (ix) the anticipated benefits and success of our collaborations; (x) the anticipated benefits of our cost savings initiatives and our ability to realize the planned savings; and (xi) other statements that are not historical facts.

Each of these forward-looking statements involves risks and uncertainties. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the risks and uncertainties associated with: (i) the impact of global and macroeconomic events, such as recent and potential future bank failures, inflation, supply chain disruptions, and the ongoing Ukraine-Russia and Israel-Hamas conflicts and related sanctions, on our business and the global economy; (ii) challenges inherent in developing, manufacturing and commercializing products; (iii) our ability to further deploy new products and applications and expand the markets for our technology platforms; (iv) third parties’ abilities to manufacture our instruments and consumables; (v) our expectations and beliefs regarding future growth of the business and the markets in which we operate; (vi) the accuracy of our estimates; (vii) our ability to obtain financing to fund our operations and continue as a “going concern”; (ix) the success of our cost savings initiatives and our ability to realize the planned savings; (x) the success of products competitive with our own; (xi) changes in our strategic and commercial plans; and (xii) the application of generally accepted accounting principles which are highly complex and involve many subjective assumptions. We are under no duty to update any of these forward-looking statements after the date of this presentation to conform these statements to actual results or revised expectations, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation. Except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements contained in this presentation.

More information about these and other statements, risks and uncertainties is contained in our filings with the U.S. Securities and Exchange Commission, including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2023 and in other filings subsequently made by us with the Securities and Exchange Commission. All forward-looking statements contained in this presentation speak only as of the date on which they were made and are based on management’s assumptions and estimates as of such date. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise except as required by law.

To supplement our financial results reported in accordance with U.S. generally accepted accounting principles (GAAP), we have provided certain non-GAAP financial measures, including gross margin and operating expense in this presentation. A description of these non-GAAP financial measures as well as a reconciliation to the nearest GAAP financial measures are included at the end of the Company’s earnings release issued associated with this presentation, which has been posted on the investor relations page of the Company’s website. Because of the non-standardized definitions of non-GAAP financial measures, the non-GAAP financial measures as used in this presentation and the associated reconciliation table have limits in its usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies. For certain non-GAAP financial measures we do not provide guidance for the most directly comparable GAAP measures and similarly we cannot provide a reconciliation between our most directly comparable GAAP measures without unreasonable effort due to the unavailability of reliable estimates for certain components which are not within our control and may vary greatly between periods and could significantly impact our financial results calculated in accordance with GAAP.

We believe that non-GAAP financial measures in this presentation are useful to investors and analysts as a supplement to our financial information prepared in accordance with GAAP for analyzing operating performance and identifying operating trends in its business. We believe these measures allow for greater transparency with respect to key financial metrics we use in assessing our own operating performance and making operating decisions. These non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read in conjunction with our consolidated financial statements prepared in accordance with GAAP.

# Bionano is transforming the way the world sees the genome

## Pioneered a method for structural variant (SV) detection called optical genome mapping (OGM)

- **OGM consolidates 3 legacy cytogenetic methods** into one assay
- **It complements sequencing** as a new tool
- **Consistently finds more actionable variants** in days vs. weeks at a substantially lower cost

## Commercial stage, tools & Dx Co with TTM of \$36.6 M in sales with platform for genome analysis

- **Strategic focus on driving growth in utilization** of OGM consumables supported by the existing install base of ~360 OGM systems
  - Revenue growth through *menu expansion* and end-to-end workflow improvements
- **Targeting academic medical centers and commercial reference labs:** research applications are cancer, cell and gene therapy, and constitutional genetic disease
- **Estimated OGM TAM:** \$10B and 10K labs running ~10M samples/year + 2.4M samples for cell and gene therapy

## Executive Team



Erik Holmlin, PhD  
President and Chief Executive Officer  
Joined 2011



Mark Oldakowski  
Chief Operating Officer  
Joined 2014



Alka Chaubey, PhD  
Chief Medical Officer  
Joined 2020

# Traditional methods in use today for SV detection are outdated and leave a significant number of questions unanswered

Traditional cytogenetics requires multiple methods that are labor intense, time-consuming, repetitive & costly



**Karyotyping**

**Up to 4** weeks for results



**FISH**

(fluorescence *in-situ* hybridization)

**4-6** different probes per sample & successive testing



**Microarrays**

**Detect CNVs** only

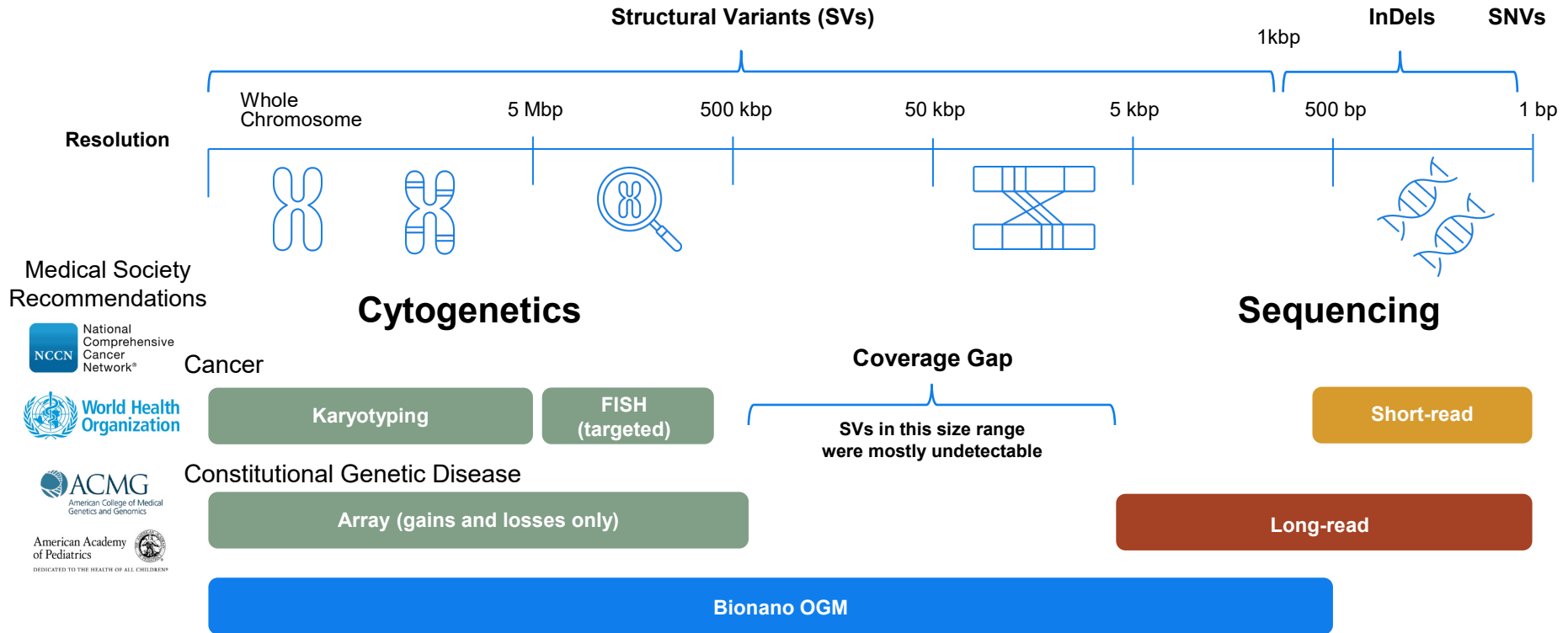
Clinical utility of traditional cytogenetic analysis is severely limited

**Only 50%** of testing is useful for guiding therapy

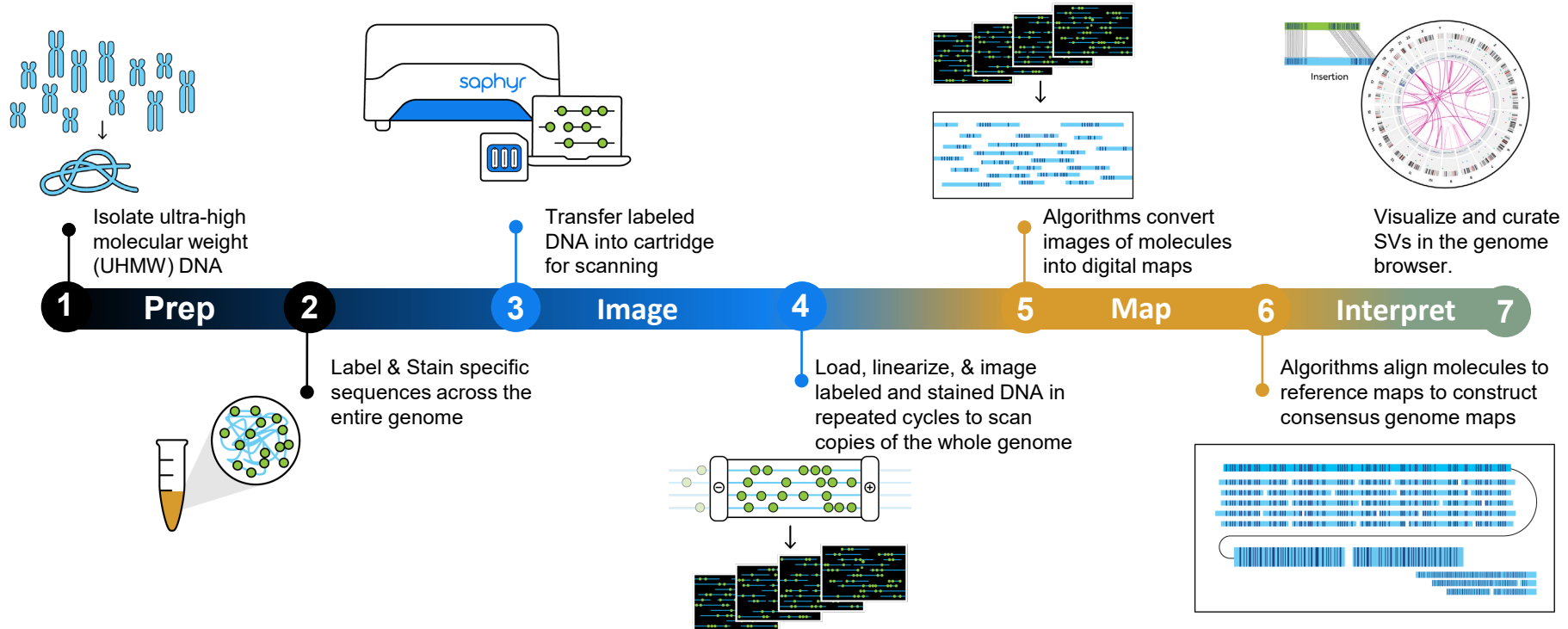
**As many as 20%** of prognostic scores for Rx selection may be wrong

**86%** of cell & gene therapy programs are halted, due partly to limitations in genome analysis tools

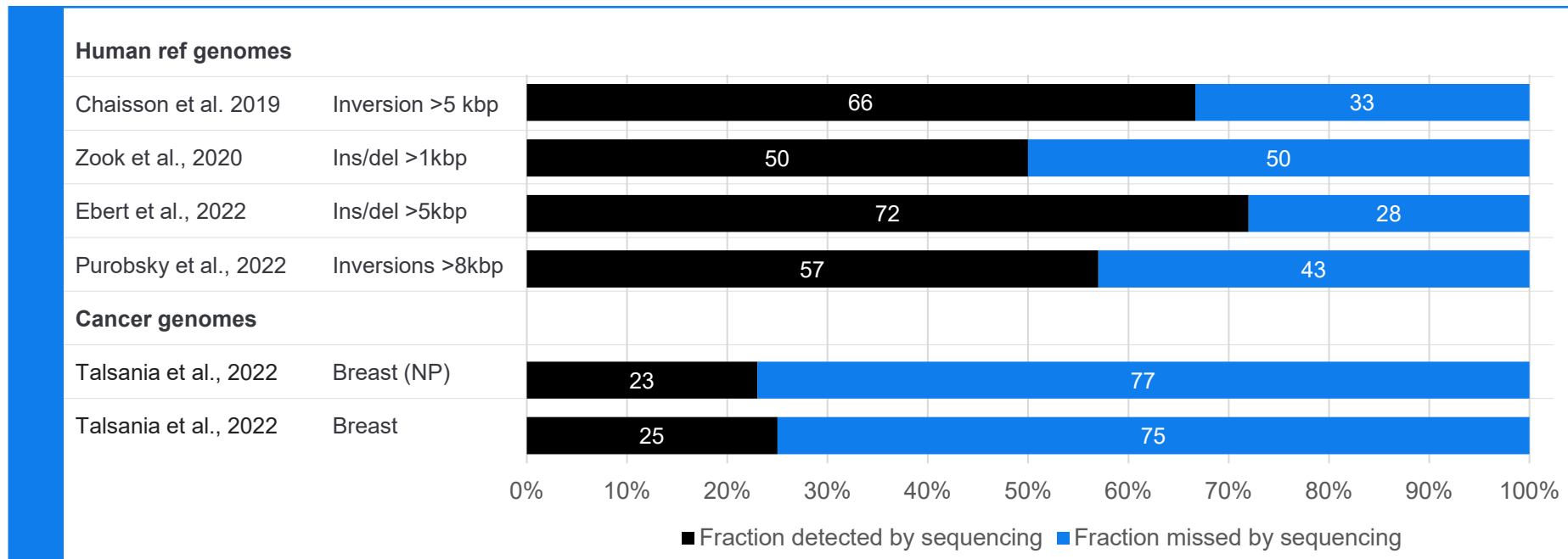
# OGM detects all classes of SVs in one assay, replacing classical cytogenetics, and bridges the gap to sequencing



# OGM uses single molecule imaging of sequence specific patterns on ultra-high molecular weight DNA to reveal SVs



# Published studies consistently show that OGM outperforms long-read sequencing for detection of structural variations



Chaisson, et al. *Nat Commun.* 2019;10(1):1784., Zook, et al. *Nat Biotechnol.* 2020;38(11):1347-1355; Ebert, et al. *Science.* 2021;372(6537). Porubsky, et al. *Cell.* 2022;185(11):1986-2005.e26. Talsania, et al. *Genome Biol.* 2022;23(1):255.

# Bionano provides an end-to-end solution for comprehensive structural variant detection with OGM



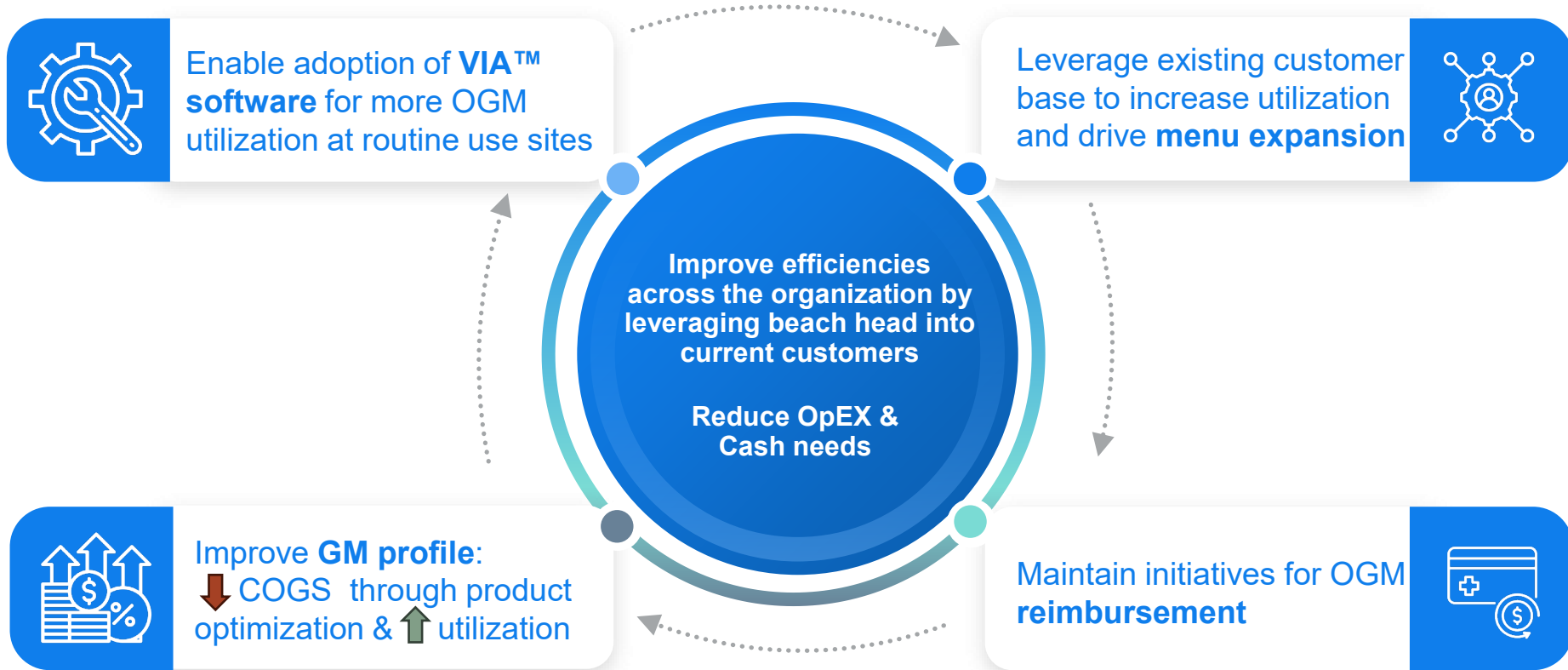
- Sample-to-interpreted report in as few as 3 days for up to 10,000 samples per year per instrument
- VIA™ software integrates OGM data for all classes of SVs together with NGS and array data in a single view
- Computation solutions developed in collaboration with NVIDIA
- Bionano sells and supports all components of the workflow



# Strategy Update: Our Plan to Succeed

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# Strategic pillars underpinning the transformed Bionano



# Key publications show evidence of OGM as a superior alternative to traditional cytogenetic methods & sequencing (NGS or LRS) for SV detection

## Heme malignancy

www.nature.com/leu Leukemia

ARTICLE OPEN [Check for updates](#)

MYELODYSPLASTIC NEOPLASM

High-resolution structural variant profiling of myelodysplastic syndromes by optical genome mapping uncovers cryptic aberrations of prognostic and therapeutic significance

Hui Yang<sup>1</sup>, Guillermo Garcia-Manero<sup>1</sup>, Koji Sasaki<sup>1</sup>, Guillermo Montalban-Bravo<sup>1</sup>, Zhenya Tang<sup>1</sup>, Yue Wei<sup>1</sup>, Tapan Kadla<sup>1</sup>, Kelly Chien<sup>1</sup>, Diana Ruzh<sup>1</sup>, Ha Nguyen<sup>1</sup>, Awadesh Kalia<sup>1</sup>, Manjunath Nimmagayalu<sup>1</sup>, Carlos Bueso-Ramos<sup>1</sup>, Hagop Kantarjian<sup>1</sup>, L. Jeffrey Medeiros<sup>1</sup>, Rajyalakshmi Luthra<sup>1</sup> and Rashmi Kanagal-Shamanna<sup>1</sup>

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- OGM prognostic scores were different for **17 to 21%** of study subjects
- OGM revealed additional pathogenic variants in **13%** of study subjects

<https://www.nature.com/articles/s41375-022-01652-8#Abs1>

## Constitutional

npj Genomic Medicine www.nature.com/npjgenmed

ARTICLE OPEN [Check for updates](#)

Application of full-genome analysis to diagnose rare monogenic disorders

Joseph T. Shieh<sup>1,2,3,4,5</sup>, Monica Penon-Portmann<sup>1,2,3,4</sup>, Karen H. Y. Wong<sup>1,2</sup>, Michal Levy Sakai<sup>1</sup>, Michelle Verhegge<sup>1</sup>, Anne Savelle<sup>1,2</sup>, Renata C. Gallagher<sup>1,2</sup>, Bryce A. Mendelsohn<sup>1,2</sup>, Jessica Terrey<sup>1</sup>, Daniel Bielefeld<sup>1</sup>, Heidi Terry<sup>1</sup>, Stephen K. Chow<sup>1</sup>, Andrew G. Shams<sup>1</sup>, Steven E. Brenner<sup>1</sup>, Zhongxia Qi<sup>1</sup>, Jingwei Yu<sup>1</sup>, Ophir D. Klein<sup>1,2,3,4</sup>, David Martin<sup>1</sup>, Pu-Yan Kwok<sup>1,2,3,4</sup> and Dario Boffelli<sup>1,2</sup>

Current genetic tests for rare diseases provide a diagnosis in only a modest proportion of cases. The Full-Genome Analysis method, FGA, combines long-range assembly and whole-genome sequencing to detect small variants, structural variants with breakpoint resolution, and phasing. We built a variant prioritization pipeline and tested FGA's utility for diagnosis of rare diseases in a clinical setting. FGA identified structural variants and small variants with an overall diagnostic yield of 40% (20 of 50 cases) and 33% in exome-negative cases (8 of 23 cases). 4 of these were structural variants. FGA detected and mapped structural variants that are missed by short reads, including non-coding duplication, and phased variants across long distances of more than 180 kb. With the prioritization algorithm, longer DNA technologies could replace multiple tests for monogenic disorders and expand the range of variants detected. Our study suggests that genomes produced from technologies like FGA can improve variant detection and provide higher resolution genome maps for future application.

npj Genomic Medicine (2021) 6:77 | <https://doi.org/10.1038/s41525-021-00241-5>



- OGM findings resolved genetic diseases that were previously undiagnosed
- OGM resulted in incremental **increase in diagnostic yield of 12%** in rare disease cohort

<https://www.nature.com/articles/s41525-021-00241-5>

## Gene therapy

Article

THE EMBO JOURNAL

Unbiased assessment of genome integrity and purging of adverse outcomes at the target locus upon editing of CD4<sup>+</sup> T-cells for the treatment of Hyper IgM1

Daniele Canarutto<sup>1,2,3,4</sup>, Claudia Asperti<sup>1,2</sup>, Valentina Vavassori<sup>1,2</sup>, Simona Porcellini<sup>1,2</sup>, Elisabetta Rovelli<sup>1</sup>, Marianna Paulis<sup>1,2</sup>, Samuele Ferrari<sup>1,2</sup>, Angelica Varesi<sup>1,2</sup>, Martina Fiumara<sup>1</sup>, Aurelien Jacob<sup>1</sup>, Lucia Sergi<sup>1</sup>, Ilaria Visigalli<sup>1</sup>, Francesca Ferrua<sup>1,2</sup>, Luis Ignacio González-Granado<sup>1</sup>, Vassilios Lougaris<sup>1</sup>, Andrea Finocchi<sup>1</sup>, Anna Villa<sup>1,2,3</sup>, Marina Radrizzani<sup>1,2</sup> & Luigi Naldini<sup>1,2,3,4</sup>



- OGM detected **11 nonrecurring SVs** outside of the target locus
- OGM analysis showed that **20-50%** of the edited cells expressing the rescued gene did not undergo precise editing

<https://www.embopress.org/doi/epdf/10.15252/embj.2023114188>

# Strategic assemblance of end-to-end OGM workflow



## Q1' 2017

Commercial launch of Saphyr® system



## Q4' 2021

Acquires BioDiscovery software solution NxClinical™ for genome-wide variant analysis from NGS and microarray data types

## Q1' 2024

Full commercial launch of Stratys™ system, which offers high throughput capabilities for new clinical and translational research applications



## Q1' 2018

Introduces DLS chemistry, method for improving its single-molecule optical genome maps

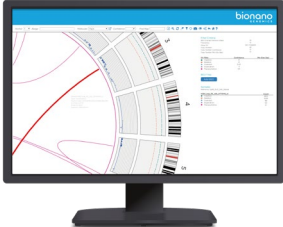


## Q4' 2022

Acquires Purigen Biosystems - automated nucleic acid extraction and purification solutions using proprietary isotachopheresis (ITP) technology on the Ionic® system; OGM kit anticipated second half 2024

## Q2' 2023

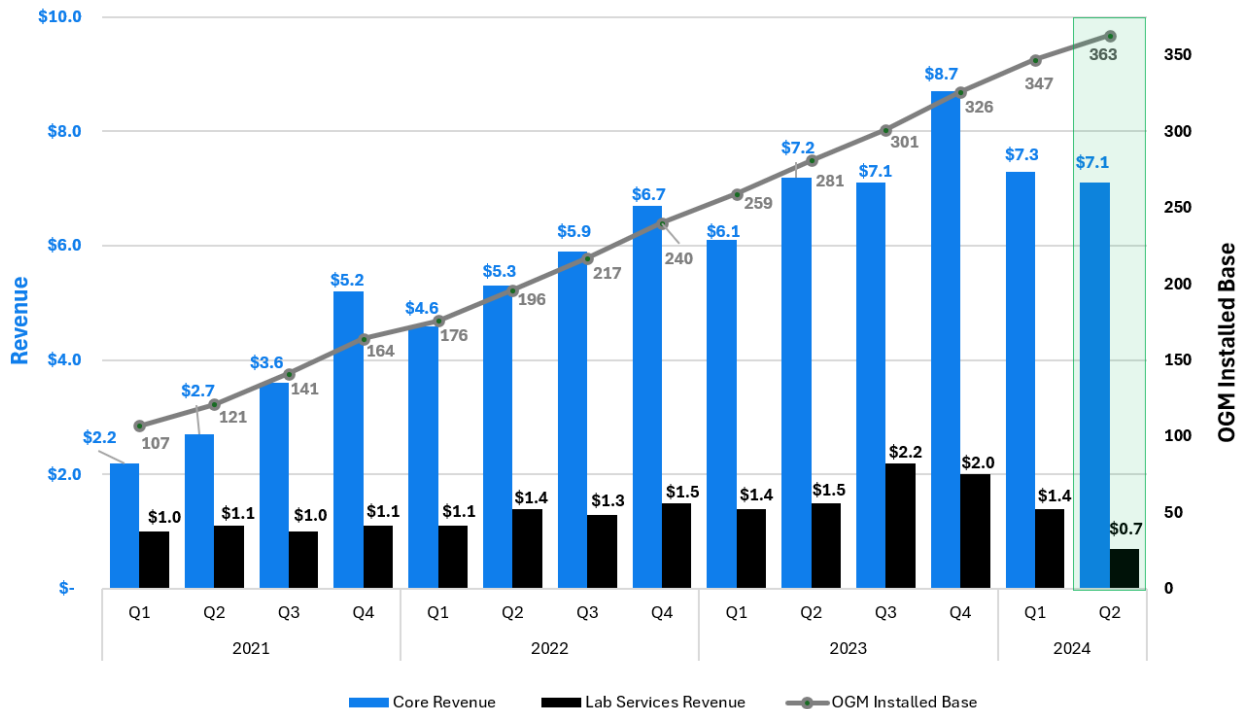
Launch of VIA™ software, a new platform for visualization, interpretation and reporting across OGM, microarray and NGS data types. Version with expanded capabilities released in May 2024



# Financial Review

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# Financial highlights as of June 30<sup>th</sup>, 2024



- TTM Revenues thru Q2: **\$36.6M** (+16% vs Q2'23)
- Q2 revenues: **\$7.8M** (-10% vs Q2'23)
- GAAP gross margin of **33%**
- GAAP OpEx **\$19.6M**
- Q2 OGM installed base: **363** (+29% vs Q2'23)
- Q2 flowcells sold: **6,165** (-13% vs Q2'23)

**\$30.3M\*** Cash, Cash Equivalents, and Available-for-Sale Securities at End Q2 2024

\*\$11.4M subject to certain restrictions

# Important steps to help us deliver against our vision



## Debt Restructuring

- ✓ Completed Private Placement of Sr. Sec Notes Due May 2026 (\$20M principal amount) in May 2024
- ✓ Proceeds used to completely retire the October 2023 convertible debt facility



## Equity Financing

- ✓ Registered direct offering in April 2024, with gross proceeds of ~\$10M
- ✓ Additional direct offering in July 2024, with gross proceeds of ~\$10M; potential additional gross proceeds of up to \$20M



## Projected Cost Savings

- ✓ \$65M to \$75M projected cumulative annual operating expense reduction by Q1 2025

A highly disciplined approach will position company for future streamlined growth

# Significant milestone for OGM with establishment of Category I CPT code for OGM in hematological malignancy analysis

- Editorial panel of the American Medical Association (AMA) established a new Category I Current Procedural Terminology (CPT) code for the use of OGM in cytogenomic genome-wide analysis to detect structural and copy number variations related to hematological malignancies
- **CPT code is a key component in obtaining reimbursement** for the Bionano Laboratories OGM-Dx™ HemeOne laboratory developed test from third party payors



## American Medical Association (AMA) CPT Code for OGM

Code #	88XX0
Final Code #	TBD
Code Type	NEW
Category	Molecular Pathology; Optical Genome Mapping
Long Code Descriptor	Cytogenomic genome-wide analysis, hematologic malignancy, structural variations and copy number variations, optical genome mapping (OGM)



# By leveraging its beachhead with current customer base, Bionano is accelerating utilization and operating efficiencies across its OGM base

## Streamlined Business Focus



- Adoption of VIA™ software driving OGM utilization across clinical sites
- Leverage existing customer / install base to increase utilization and drive menu expansion
- Maintain initiatives for OGM reimbursement
- Improve GM profile: COGS & Sample pull through

## 2024 Guidance



**FY'24 Total Revenue Guidance:**  
**\$32-\$36M (revised)**



**OGM Installed Base YE'24:**  
**381 – 401 systems**



**3Q'24 Revenue Guidance:**  
**\$7.9 – \$8.9M**



**Thank you.**

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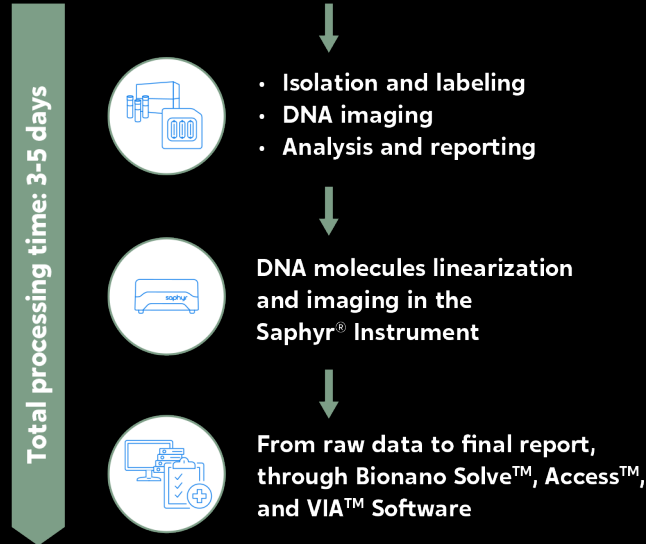
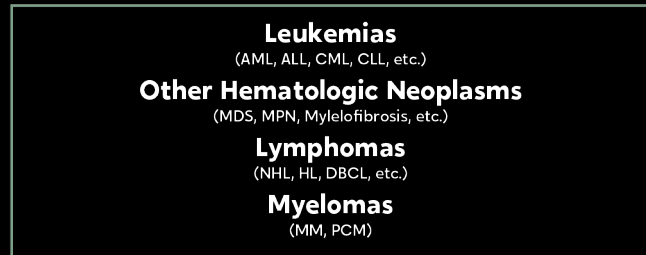
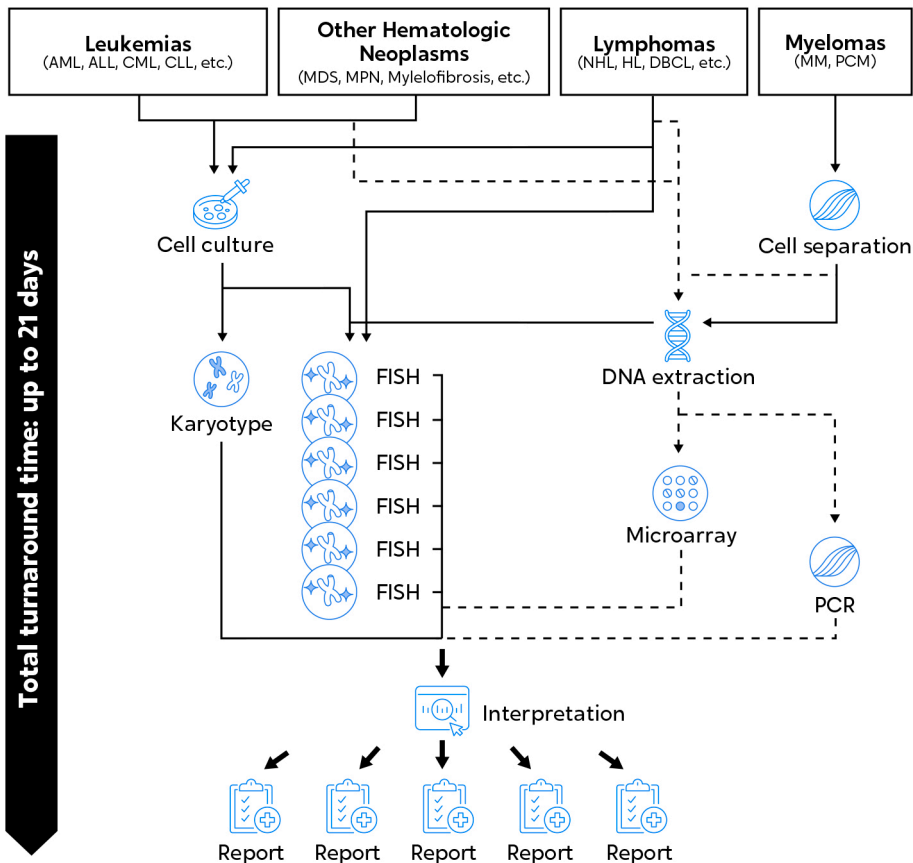
## Primary Appendix

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# Traditional Cytogenetic Lab Workflow

Vs.

# The OGM Workflow



# OGM Has a Unique Position in the Genomics Market

## NGS Landscape



illumina  
Solexa



ULTIMA  
GENOMICS  
UG 100



Element  
Biosciences  
AVITI



PacBio  
Onso



SINGULAR  
GENOMICS  
G4



illumina  
Novaseq

## LRS Landscape



Oxford  
NANOPORE  
PROMETHION 24



Revio

## OGM Landscape



Saphyr system



Stratys system

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# Clinical Trial Sites and PIs Influence Guidelines and Reimbursement



Brynn Levy, PhD  
Columbia

Board ISPD, Co-Editor Prenatal  
Diagnosis, CGC Founding Member



Aaron Bossler, MD, PhD  
University of Iowa

AMA CPT Editorial Committee  
Member



Rashmi Kanagal-Shamanna  
MD Anderson

AMP BOD, CGC BOD, NCCN Liaison



AUGUSTA  
UNIVERSITY

Ravindra Kolhe, MD, PhD  
Augusta University

US and Canadian CAP, AACR/ASCO  
visibility, NCI match PI, TSO500  
driver for Illumina



Adrian Dubuc, PhD  
Harvard

Former CGC president, and Harvard



Barb Dupont, PhD,  
Greenwood Genetic Center

Constitutional (Agilent validation, Affy  
validation, Illumina FDA sequencing  
validation consortium)



Jim Broach, PhD  
Penn State Medical College

Track record of success with  
Bionano technology



Gordana Raca, PhD  
CHLA

CGC President, NCCN Liaison  
ACMG Technical Standards



Saurabh Gupta, PhD  
Quest – Med Fusion

Quest, high volume



Anwar Iqbal, PhD  
University of Rochester

CGC Founder, NY state



Yasmine Akkari, PhD  
Nationwide Childrens

AMCG lab QA, AMP training and  
ed chair, CGC President



Ulrich Broeckel, MD  
Medical College of Wisconsin

NIH initiatives on clinical  
pharmacogenomics



Stephen C. Peiper, MD  
Chairman & Senior Vice President of  
Enterprise Pathology



Roger Stevenson, MD  
Founder of Greenwood  
Genetic Center

World renowned geneticist



Aleksandar Rajkovic, PhD, MD  
UCSF Chief Genomics Officer

Stuart Lindsay Distinguished Professor in  
Experimental Pathology



Teresa Smolarek, PhD  
Cincinnati Children's Hospital

Director, Genetics and Genomics  
Diagnostic Laboratory



Peter Bui, PhD, FACMG  
Quest Diagnostics

National Chief Director,  
Cytogenetics



James S Blachly, MD  
Comprehensive Cancer Center OSU

National Comprehensive Cancer  
Network

# Recent Publications from Our Clinical Trials Span our Target Markets

REFERENCE	COHORT SIZE	Genetic Disease			Cancer				
		FSHD	Prenatal	Postnatal	AML/CML//MP N/MDS	ALL/CLL	Lymphoma	MM/PCM	Solid Tumor
<a href="#">University of Iowa</a> Stence, et al., 2021	351	●							
<a href="#">University of Augusta</a> Sahajpal, et al., 2023	114		●						
<a href="#">Ningbo Women &amp; Children</a> Xie, et al., 2024	204		●						
<a href="#">Multisite trial</a> Iqbal, et al., 2023	404			●					
<a href="#">Multisite trial</a> Broeckel, et al., 2024	597			●					
<a href="#">Radboud University</a> Neveling et al., 2021	52				●	●		●	
<a href="#">Multi-site</a> Pang et al. 2022	80				●	●	●	●	
<a href="#">Augusta, Emory</a> Sahajpal et al. 2022	69				●		●	●	
<a href="#">M.D. Anderson</a> Yang et al., 2022	101				●				
<a href="#">Cancer Genomics Consortium</a> Levy et al., 2022	100				●				
<a href="#">Hannover Medical School</a> Lühmann et al., 2023	142					●			
<a href="#">Penn State Med</a> Goldrich et al., 2021	20								●

● Peer-reviewed